EXHIBIT 33

K073257

510(k) SUMMARY

1. **Submitter**

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Shinagawa-Ku, Tokyo 140 Japan
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Contact: Mr. Kuroiwa

Authorized Contact

Kawasumi Laboratories America, Inc.
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Tampa, Fl 33610
Phone: 813-630-5554
Fax: 813-630-5033
Contact: Mr. Jack Pavlo

MAY - 5 2008

2. **Name of Device**: Winged Needle Sets with an Antineedle Stick Protector

Three previously cleared to market 510(k) devices are designed with an integral antineedle stick protector that provides a safety feature intended to minimize accidental needle stick injuries when the device is activated during removal from the patient.

1. 510(k) Number: K873421, Name: Kawasumi A.V. Fistula Set
2. 510(k) Number: K001043, Name: Kawasumi Laboratory Blood Drawing Kit
3. 510(k) Number: K994323, Name: Kawasumi Laboratories Phlebotomy Set

3. **Predicate Device**: Medisytems Mastergurd Arterial Venous Fistula Set (K932074), Kawasumi A.V. Fistula Set (K873421), Kawasumi Laboratory Blood Drawing Kit (K001043), and Kawasumi Laboratories Phlebotomy Set (K994323)

4. **Description of the Device**: The design of the three previously cleared to market 510(k) devices has not changed except to add the integral antineedle stick protector. The antineedle stick protector is a polymeric device designed to be used integral with the wing and needle and shields the needle when the needle with hub and wing assembly is removed from the patient

5. **Intended Use**:

   1. 510(k) Number: K873421
      Name: Kawasumi A.V. Fistula Set
      Intended Use: This device is intended to be used to access a vein or artery and to be used as a conduit to connect to blood tubing lines for performing patient hemodialysis. The device is designed with an integral antineedle stick protector that provides a safety feature intended to minimize accidental needle stick injuries when the device is activated during removal from the patient's vein or artery.

   2. 510(k) Number: K001043
      Name: Kawasumi Laboratory Blood Drawing Kit
      Intended Use: This is a therapeutic device used to access a patient's vein for blood removal from the patient to a blood bag reservoir to aid in the treatment of a disease or other condition. This device is not intended for blood transfusions. The device is designed with an integral antineedle stick protector that provides a safety feature intended to minimize accidental needle stick injuries when the device is activated during removal from the patient's vein.

3. 510(k0 Number: K994323
   Name: Kawasumi Laboratories Phlebotomy Set
   Intended Use: This device is intended to be used to access a patient's vein and as a conduit for blood removal to a vacuum bottle to aid in the treatment of a disease or other condition. The device is designed with an integral antineedle stick protector that provides a safety feature intended to minimize accidental needle stick injures when the device is activated during removal from the patient's vein.

6.Technological Characteristics: The Antineedle Stick Protector is substantially equivalent to the Medisystems Masterguard Sets. The antineedle stick protector is activated in a different manner than the Medisystems Masterguard Set, but achieves the same results. In both devices, the needle tip is protected inside the device after use.

7. **Performance Data**: Kawasumi Laboratories has conducted a successful simulated use study to determine the acceptability of this device for use to minimize accidental needlestick injuries. Kawasumi Laboratories believes the successful simulated use study shows the device is suitable for its intended use and is substantially equivalent to the predicate device.

8. **Conclusions**: The device is as safe as the predicate device and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

Kawasumi Laboratories, Incorporated
C/O Mr. Jack Pavlo
Authorized Representative
Kawasumi Laboratories America, Incorporated
4723 Oak Fair Boulevard
Tampa, Florida 33610

Re: K073257
Trade/Device Name: Kawasumi Laboratories Large Wing Sets with Antineedle Stick Protector
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: November 16, 2007
Received: November 23, 2007

Dear Mr. Pavlo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____K073257_____

Device Name:_Kawasumi Laboratories Large Wing Sets with Antineedle Stick Protector

Indications For Use:

Name: Kawasumi A.V. Fistula Set
Intended Use: This device is intended to be used to access a vein or artery and to be used as a conduit to connect to blood tubing lines for performing patient hemodialysis. The device is designed with an integral antineedle stick protector that provides a safety feature intended to minimize accidental needle stick injuries when the device is activated during removal from the patient's vein or artery.

Name: Kawasumi Laboratory Blood Drawing Kit
Intended Use: This is a therapeutic device used to access a patient's vein for blood removal from the patient to a blood bag reservoir to aid in the treatment of a disease or other condition. This device is not intended for blood transfusions. The device is designed with an integral antineedle stick protector that provides a safety feature intended to minimize accidental needle stick injuries when the device is activated during removal from the patient's vein.

Name: Kawasumi Laboratories Phlebotomy Set
Intended Use: This device is intended to be used to access a patient's vein and as a conduit for blood removal to a vacuum bottle to aid in the treatment of a disease or other condition. The device is designed with an integral antineedle stick protector that provides a safety feature intended to minimize accidental needle stick injures when the device is activated during removal from the patient's vein.

Prescription Use ___x____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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